### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA \*

\*

v. \* CRIMINAL NO. RWT-10-0694

\*

LAUREN STEVENS,

\*

**Defendant** 

\* \* \*\*\*\*

## GOVERNMENT'S OPPOSITION TO DEFENDANT'S MOTION FOR BILL OF PARTICULARS

The United States of America opposes the motion of the defendant, Lauren Stevens, for a Bill of Particulars (DE 23) on the ground that the detailed 19-page speaking indictment more than adequately sets forth the basis for the charges in this case and gives the defendant ample notice of the charges against her. The grounds for this opposition are further set forth as follows:

### I. THE CHARGED CONDUCT AND DISCOVERY PROVIDED

The indictment sets forth specific allegations that the defendant engaged in an effort to deceive the United States Food and Drug Administration ("FDA") and obstruct the FDA's investigation into the off-label promotion of the drug Wellbutrin by her employer at the time, GlaxoSmithKline ("GSK").¹ The indictment alleges that in October 2002, the FDA asked for information about the company's promotion of a prescription drug as part of an investigation into whether the drug was being promoted for uses that had not been approved by the FDA as safe and effective for those uses. *See* Indictment, Introductory Allegations ¶ 3. Data demonstrating a

<sup>&</sup>lt;sup>1</sup>The indictment did not identify Stevens' employer or the drug involved. Since that time, GSK has publicly acknowledged that it was Stevens' employer at the time of the events alleged and that the drug in question is Wellbutrin.

drug's safety and efficacy for a particular use is required for FDA approval. Federal law forbids the marketing or promotion of drugs for unapproved – or "off-label" – uses. *See id.* ¶¶ 6-9.

The indictment further alleges that from February 2003 through November 2003, in response to the FDA's inquiry, Stevens signed and sent a series of letters from GSK to the FDA that falsely denied that GSK had promoted Wellbutrin for off-label uses, even though she knew, among other things, that GSK had sponsored numerous programs where Wellbutrin was promoted for unapproved uses. The indictment alleges that Stevens knew that GSK had paid numerous physicians to give promotional talks to other physicians that included information about unapproved uses of Wellbutrin. *See id.* ¶¶ 16-24, 29-30, 41. According to the indictment, GSK paid one such physician to speak at 511 promotional events in 2001-2002 and another physician to speak at 488 such events during that time period. *See id.* ¶¶ 21-24.

The indictment also alleges that Stevens did not provide the FDA with slide sets used by the physicians who were paid by GSK to promote Wellbutrin, even though the FDA had asked for the slide sets and Stevens had previously promised to obtain and provide the FDA with such materials. *See id.* ¶¶ 12-13, 18, 27, 34-36, 39. The indictment alleges that a legal memorandum was prepared for Stevens that set forth the "pros" and "cons" of producing these slide sets to the FDA. *See id.* ¶ 35. According to the indictment, one of the "cons" was that the slide sets would provide "incriminating evidence about potential off-label promotion of [Wellbutrin] that may be used against [GSK] in this or in a future investigation." *See id.* Stevens did not provide the FDA with the slide sets, but represented to the FDA that GSK's responses to the FDA's requests were "final" and "complete." *See id.* ¶ 36.

The indictment identifies in detail the false statements alleged in each 18 U.S.C. § 1001

count and the course of conduct, including those specific false statements, that is the core of the obstruction of justice charges. This includes alleging that Stevens specifically identified the incriminating documents, requested a memorandum on the pros and cons of producing them, and then decided not to produce them, even though she had promised in writing to produce them and represented to the FDA that her responses as of May 21, 2003 were "final" and "complete." *See id.* ¶¶ 20, 34-37. The indictment also specifies that Stevens knew of and deliberately removed from certain documents produced to the FDA the columns that listed the entertainment and compensation provided to attendees of GSK's speaker programs, and made representations to the FDA that no such remuneration was provided to the attendees of those events. *See id.* ¶¶ 32-33; *see also id.* at Count IV.

In addition, the government has provided Stevens with significant discovery, including numerous documents, videos, CDs/DVDs, memoranda of interviews, and testimony. In particular, this discovery includes memoranda of interviews and notes of two proffer sessions with Stevens, which should give Stevens additional information about the issues of concern to the government. The discovery provided to Stevens in December 2010 included ten binders of materials directly relating to Stevens' response to the FDA's investigation, organized with separate sections by issue (*e.g.*, documents regarding the physician referenced in ¶¶ 21-22 of the indictment) and with separate sections that contain the handwritten notes of each attorney and paralegal involved in preparing the responses to the FDA. The binders are copies of binders GSK provided to the government and, although a small subset of the materials being made available to Stevens, contain most of the relevant documents. The discovery provided in December also included a searchable database containing 76,413 pages of documents GSK deemed directly relevant to its response to the FDA. At the defendant's request, in January 2011

the government also produced much larger searchable databases of documents. This information, coupled with the allegations in the indictment, provide more than sufficient information to fulfill the purposes of a bill of particulars.

# II. A BILL OF PARTICULARS IS NOT WARRANTED WHERE, AS HERE, THE INDICTMENT ALLEGES THE ESSENTIAL ELEMENTS OF THE CRIME AND PERMITS THE DEFENDANT TO PREPARE A DEFENSE

# A. <u>An Indictment That Alleges the Essential Elements of the Crime and Permits</u> the Defendant to Prepare a Defense Is Sufficient

Stevens is not entitled to a bill of particulars because the detailed 19-page speaking indictment more than adequately sets forth the essential elements of the crimes and permits her to prepare her defense. A defendant is not entitled to a bill of particulars as a matter of right. *Wong Tai v. United States*, 273 U.S. 77, 82 (1927). Nor is a bill of particulars intended to serve as the equivalent of answers to interrogatories in a civil case. Rather, "a bill of particulars is a defendant's means of obtaining specific information about charges brought in a vague or broadlyworded indictment." *United States v. Dunnigan*, 944 F.2d 178, 181 (4th Cir. 1991) (citing *United States v. Debrow*, 346 U.S. 374, 378 (1953)), *rev'd on other grounds*, 507 U.S. 87 (1993). As the First Circuit explained in *United States v. Sepulveda*, 15 F.3d 1161, 1192-1193 (1st Cir. 1993):

Motions for bills of particulars are seldom employed in modern federal practice. When pursued, they need be granted only if the accused in the absence of a more detailed specification, will be disabled from preparing a defense, caught by unfair surprise, or hampered in seeking the shelter of the Double Jeopardy Clause.

An indictment is sufficient if it alleges the essential elements of the crime with which the defendant is charged in a manner that permits the defendant to prepare a defense and plead double jeopardy in any future prosecution for the same offense. *Hamling v. United States*, 418 U.S. 87, 117 (1974); *United States v. Hooker*, 841 F.2d 1225, 1227 (4th Cir. 1988); *United States* 

v. American Waste Fiber Co., 809 F.2d 1044, 1046 (4th Cir. 1987). As long as the indictment fulfills these purposes, a bill of particulars is unnecessary and its denial does not constitute an abuse of discretion. United States v. Butler, 885 F.2d 195, 199 (4th Cir. 1989); United States v. Jackson, 757 F.2d 1486, 1491 (4th Cir. 1985). If the indictment is deficient, the "purpose of a bill of particulars is to enable the defendant to obtain sufficient information on the nature of the charges against him so that he may prepare for trial, minimize the danger of surprise at trial, and enable him to plead his acquittal or conviction in bar of another prosecution for the same offense." United States v. Schembari, 484 F.2d 931, 934-35 (4th Cir. 1973). Accord United States v. Dulin, 410 F.2d 363, 364 (4th Cir. 1969). But if, as here, the indictment fully and amply complies with the requirements of the Fifth and Sixth Amendments and Fed. R. Crim. P. 7(c), "[a] bill of particulars is not to be used to provide detailed disclosure of the government's evidence in advance of trial." United States v. Automated Medical Laboratories, Inc., 770 F.2d 399, 405 (4th Cir. 1985). As the Third Circuit has stated:

A bill of particulars, unlike discovery, is not intended to provide the defendant with the fruits of the government investigation. . . . Rather, it is intended to give the defendant only that minimum of information necessary to permit the defendant to conduct his *own* investigation.

*United States v. Smith*, 776 F.2d 1104, 1111 (3d Cir. 1985) (citations omitted; emphasis in original).

# B. This Indictment Alleges the Essential Elements of the Crime and Permits the Defendant to Prepare Her Defense

The indictment here is more than sufficient. This is no bare bones indictment; the specifics of the charges are clear. As the defendant has acknowledged, the indictment specifies false statements she is charged with making and documents she is charged with concealing. *See* Defendant's Memorandum of Law in Support of Motion at p. 4 n.6 (DE 23-1). The indictment

provides specific examples of documents deliberately withheld, of information deleted from spreadsheets provided to the FDA, and of the defendant's specific consideration of whether to produce such information. *See* Indictment, Introductory Allegations ¶¶ 19, 22, 24, 32-36; Count IV ¶ 3. The indictment even quotes from a memorandum prepared for the defendant at her request that enumerates the pros and cons of producing the promised documents.<sup>2</sup> *See* Indictment, Introductory Allegations ¶ 35. Nonetheless, the defendant asks this Court to order the government to identify each false and misleading statement the defendant made to the FDA, the falsified and altered documents the defendant sent to the FDA, and the documents, tangible objects, and other information the defendant withheld, concealed, and covered up from the FDA. *See* Defendant's Motion at p. 2 (DE 23).

The defendant is not entitled to any greater detail regarding the allegations in the indictment. Where, as here, the indictment "sets forth the elements of the offense charged and sufficiently apprises the defendant of the charges to enable him to prepare for trial," a bill of particulars is not warranted. *United States v. Fassnacht*, 332 F.3d 440, 446 (7th Cir. 2003) (citation omitted). Accordingly, the indictment, which sets forth the elements of each of the offenses and the relevant time periods, is sufficient to enable the defendant to prepare her defense, avoid surprise at trial, and protect against double jeopardy. Stevens is not entitled to more than the ample explanations and notice that the government has already provided through the indictment and discovery.

<sup>&</sup>lt;sup>2</sup>Defendant notes that the government has identified the specific false statements which are charged in the four counts alleging violations of 18 U.S.C. § 1001. Nonetheless, the government submits that the evidence of additional false statements, misleading statements, material omissions, and withholding and alteration of evidence is relevant to the proof of the § 1001 charges because, among other reasons, it demonstrates Stevens' state of mind and intent. A bill of particulars is not warranted to provide a roadmap of the evidence the government may offer in support of the clearly pleaded charges.

### C. <u>A Bill of Particulars Is Not Warranted Where the Government</u> Has Provided the Defendant with Extensive Discovery

Even if the indictment were deficiently vague, which is far from the case here, a bill of particulars would be unnecessary because the defendant has received sufficient information to prepare for trial in the form of the discovery the government has produced. "It is well established that if the government has provided the information called for in some other satisfactory form, then no bill of particulars is required." *United States v. Vasquez*, 867 F.2d 872, 874 (5th Cir. 1989). *See also United States v. Amend*, 791 F.2d 1120, 1125-26 (4th Cir. 1986); *United States v. Chen*, 378 F.3d 151, 163 (2d Cir. 2004); *United States v. Kunzman*, 54 F. 3d 1522, 1526 (10th Cir. 1995); *Sepulveda*, 15 F.3d at 1193.

The government has provided the defendant with extensive discovery, including the documents produced by GSK, relevant third parties, and relevant documents from the FDA. In addition, the government has produced the relevant grand jury and other witness testimony and many relevant interview reports. Although this is a large volume of material, most of it has been provided to the defendant in searchable databases, *i.e.*, in the same format in which it is available to the government. Furthermore, the government has provided the defendant with a road map in the form of the documents organized by witness and issues, all of the letters and communications that are at issue, the memoranda prepared by the FDA at the time, and the interview reports and testimony of witnesses, including the defendant's own proffers. During discussions with defense counsel, the government has also already identified some additional statements in the defendant's letters to the FDA that were false and/or misleading (albeit not charged as 18 U.S.C. § 1001 violations), including (1) the statements and omissions concerning continuing medical education ("CME") with respect to Wellbutrin and (2) the representations that less than 1% of the Wellbutrin speaker programs had off-label topics, but that Stevens did not know if the actual

presentations were in fact off-label.

This is not a case in which a defendant on the outskirts of a conspiracy, for example, is struggling to grasp the nature of the criminal conduct that has been charged. Stevens was in charge of GSK's response to the FDA inquiry. Stevens led GSK's investigation. Stevens signed the letters. Stevens directed the deletion of the entertainment column from the spreadsheets of speaker programs provided to the FDA. Stevens well knows which slides sets were withheld. Stevens collected the slide sets, reviewed them, requested the memorandum summarizing the "pros" and "cons" of producing them, and made the decision not to produce them.

The Fourth Circuit affirmed a district court's denial of a more detailed bill of particulars where the government gave the defendants copies of all grand jury testimony, access to all documents subpoenaed from non-defendants, documents voluntarily submitted to the government by third parties during the investigation, all available Brady material, trial exhibits (30 days before trial), a witness list (14 days before trial), and Jencks Act material (14 days before trial). *United States v. Society of Independent Gasoline Marketers*, 624 F.2d 461, 466 (4th Cir. 1979). In the instant case, the government provided Stevens with all of the above – except, to date, a witness list and trial exhibits – *months* before the trial date and provided most of it in a searchable format. Moreover, the government, was ordered to provide Stevens with a tentative witness list on March 7, 2011, and an initial exhibit list by March 14, 2011. The government has also provided all of the exhibits to the grand jury and sworn statement transcripts, which are likely to make up many of the relevant exhibits in this case. The fulsome recitation in the indictment, combined with the extremely generous discovery provided by the government, is

more than sufficient to allow defendant to prepare adequately for trial.<sup>3</sup>

### D. <u>A Bill of Particulars Is Not Appropriate to Limit or Freeze the Government's</u> Proof at Trial

A bill of particulars also should not be used as a tool to limit the government's proof at trial. United States v. Feola, 651 F. Supp. 1068, 1132 (S.D.N.Y. 1987) ("Because a bill of particulars confines the government's proof to particulars furnished, requests for a bill of particulars should not be granted where the consequence would be to restrict unduly the government's ability to present its case."). A defendant may not use a bill of particulars "to conduct discovery of the government's theory of a case, to force detailed disclosure of the facts underlying a charge, or to restrict the government's proof at trial." *United States v. Mannino*, 480 F. Supp. 1182, 1185 (S.D.N.Y. 1979). See also Automated Medical Laboratories, Inc., 770 F.2d at 405 ("bill of particulars is not to be used to provide detailed disclosure of the government's evidence in advance of trial"); United States v. Rosenthal, 793 F.2d 1214, 1227 (11th Cir. 1986) (government not required to provide defendant with all overt acts that might be presented at trial); United States v. DiCesare, 765 F.2d 890, 897 (9th Cir. 1985) (defendants could not obtain the names of any unknown conspirators, discover the exact date on which the conspiracy began, or discover all overt acts by means of a bill of particulars); *United States v.* Johnson, 504 F.2d 622, 628 (7th Cir. 1974) (bill of particulars does not entitle defendants to purely evidentiary matters); United States v. Persico, 621 F.Supp. 842, 868 (S.D.N.Y.), aff'd, 774 F.2d 30 (2d Cir. 1985) (defendants not entitled to discover means by which the government claims they performed acts in furtherance of the conspiracy charged, nor the evidence which the

<sup>&</sup>lt;sup>3</sup>The fact that the defendant believes that she and her counsel can adequately prepare for trial is also reflected by their decision to press forward with the April 5, 2011 trial date which they originally requested, and to rescind their request for a continuance.

government intends to adduce to prove their criminal acts, nor details as to how and when the conspiracy was formed).

Finally, a motion for a bill of particulars should be denied where the defendant is inappropriately seeking to require the government to "weave the information at its command into the warp of a fully integrated trial theory for the benefit of the defendants. . . ." *United States v. Addonizio*, 451 F.2d 49, 64 (3d Cir. 1971). Similarly, meritless motions should be denied to avoid "freezing" the government's evidence in advance of trial. Such freezing comes about because of the rule that requires proof at trial to conform to the particulars furnished in a bill. *See United States v. Boffa*, 513 F. Supp. 444, 485 (D. Del. 1980) (citations omitted).

Against this background, Stevens' motion is without merit. Having been provided with a detailed indictment and comprehensive discovery, Stevens is asking for even more evidentiary detail. The original Supreme Court cases on bills of particular and the more recent circuit and district cases cited above reject what Stevens is seeking here – essentially a line-by-line explanation of what is false or fraudulent in each of the letters. *See Wong Tai*, 273 U.S. at 82; *United States v. Wilson*, 565 F. Supp. 1416, 1438-39 (S.D.N.Y. 1983), *aff'd*, 750 F.2d 7 (2d Cir. 1984). This is not a case where the defendant has little knowledge of the facts underlying the charges. Stevens led GSK's response to the FDA inquiry that is at issue in the case. In addition, both before and after indictment, her counsel have engaged in extensive discussion with government counsel about the charges.

Indeed, Steven's motion essentially demands that the government lock in place and disclose, before trial, a complete opening and closing statement and trial presentation. Stevens is not entitled to a line item presentation of the government's evidence. The indictment makes perfectly clear what the grand jury alleges she did. The law does not require the government to

compartmentalize each and every act of the defendant in a bill of particulars.

#### **CONCLUSION**

Based upon the foregoing, the defendant's motion for a bill of particulars should be denied.

Dated: February 25, 2011 Respectfully submitted,

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#### CERTIFICATE OF SERVICE

I hereby certify that on February 25, 2011, a copy of the foregoing United States'

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